K120125

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OCT 3 2012

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	October 31, 2011
Submitter:	GE Medical Systems Information Technologies, Inc. 8200 West Tower Ave. Milwaukee, WI 53223
Primary Contact Person:	Robin Martin Regulatory Affairs Leader GE Medical Systems Information Technologies, Inc. Phone: (414) 336-9228 Fax: (414) 362-2585
Secondary Contact Person:	Doug Kentz Regulatory Affairs Director GE Medical Systems Information Technologies, Inc. Phone: (414) 581-8987 Fax: (414) 362-2585
Device: Trade Name:	SOFT-CUF, CLASSIC-CUF, DURA-CUF, SENSA-CUF Blood Pressure Cuffs
Common/Usual Name:	Blood Pressure Cuff
Classification Names:	Blood Pressure Cuff
Product Code:	DXQ
Predicate Device(s):	K974080 Soft Blood Pressure Cuff K022482 SENSA CUFF
Device Description:	Non-Invasive Blood Pressure cuffs incorporate an inflatable non-distensible bladder, sized to encircle a patient's limb. This allows air to flow in and out of the cuff for inflation and deflation. Inflation allows for the occlusion of an artery. The Non-Invasive Blood Pressure Cuffs facilitate the measurement of automated and manual non-invasive blood pressure (NIBP).

Intended Use: Indirect measurement of blood pressure

Technology: Adult and pediatric CLASSIC-CUF and SOFT-CUF (limited reuse cuffs or single patient use cuffs), as well as DURA-CUF and SENSA-CUF (reusable cuffs) will now be offered with a fused dual tube bayonet system (referred to as 'CLICK-IT' or 'Click' throughout documentation).

Neonatal CLASSIC-CUF and SOFT-CUF cuffs will now be offered with a unique disconnect connection system (referred to as 'SNAP-IT', 'snap' or 'Neo Snap' connector throughout documentation).

The Non-Invasive Blood Pressure Cuffs employ the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Non-Invasive Blood Pressure Cuffs and its applications comply with voluntary standards as detailed in Section 9 of this premarket submission. Cumulative changes to the Non-Invasive Blood Pressure Cuffs in addition to the offering of new connection systems require the submission of a premarket notification. The following quality assurance measures were applied to the development of the devices:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Performance testing (Verification)

Summary of Clinical Tests:

The subject of this premarket submission, Non-Invasive Blood Pressure Cuffs, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Non-Invasive Blood Pressure Cuffs to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 3 2012

GE Medical Systems Information Technologies, Inc.
c/o Mr. Jeff D. Rongero
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K120125
Trade/Device Names: CLASSIC-CUF, SOFT-CUF, DURA-CUF, SENSA-CUF
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood pressure cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: September 17, 2012
Received: September 18, 2012

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120125

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GE Healthcare

510(k) Premarket Notification Submission

510(k) Number (if known): Unknown

Device Name: Non-Invasive Blood Pressure Cuffs

Indications for Use:

GE CRITIKON blood pressure cuffs are accessories used in conjunction with noninvasive blood pressure (NIBP) measurement systems. SOFT-CUF and CLASSIC-CUF cuffs and inflation systems are non-sterile and limited reuse (may be single-patient use or optional limited reuse). They are available in neonatal, pediatric and adult sizes. DURA-CUF and SENSA-CUF cuffs and inflation systems are non-sterile and may be reused. They are available in pediatric and adult sizes. The devices are not designed, sold or intended for use except as indicated.

Prescription Use__X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_ _ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120125